

REMARKS/ARGUMENTS

Reconsideration of this patent application is respectfully requested in view of the following remarks. Claims 1, 9 and 19-21 are in the application.

The Examiner rejected claims 1, 9 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Wagu in view of Koulbanis et al. Applicants respectfully traverse.

The Examiner states that one of ordinary skill in the art would recognize that the problem of oxidation of omega-3 fatty acids and the problem of oxidation of omega-6-fatty acids are similar problems arising from the same chemical cause, namely, the double bonds in the alkene chain of the fatty acids. The Examiner states that one of ordinary skill in the art would recognize that the complexation methods of Wagu et al. are also useful for stabilizing other polyunsaturated fatty acids that are susceptible oxidation, for example, linoleic acid as described by Koulbanis.

Applicants respectfully traverse. A teaching related to omega-3 fatty acids is not necessarily an obvious teaching to solve problems with omega-6 fatty acids, just because both enclose a double bond. One of skill in the art is aware of the theories of complexation with cyclodextrins, according to which these molecules are always seen as a ring with a hydrophobic cavity and a hydrophilic exterior. The molecules to be complexed have to fit into the inner cavity of the CD molecules. Depending on the place of the double bond, the kink in the fatty acid molecule which occurs at a double bond is at different places in the molecule, resulting in different complexing behaviors depending on the place of the double bond in the molecule as well as on the length of the fatty acid. From this point of view, one of skill in the art is aware that a teaching related to complexing omega-3 fatty acids with CDs is normally not helpful to predict how omega-6-fatty acids can be complexed by CDs. In fact, as shown in the following, the teaching for omega-3 fatty acids in Wagu does not disclose any of the claimed features of the independent claims in the present application.

The present claims claim a preparation comprising a very limited and clearly defined complex:

the complex consists of an omega-6 polyunsaturated fatty acid and an alpha cyclodextrin in a ratio of 3 mol alpha CD to 1 mol of omega-6 polyunsaturated fatty acid or in a ratio of 4 mol alpha CD to 1 mol of omega-6 polyunsaturated fatty acid.

Only these complexes with the compounds in this very limited ratio (3:1 and 4:1) have the advantages presented in the present application. This ratio is not disclosed by Wagu. Wagu teaches the use of alpha, beta and gamma CDs. There is no hint to the advantage of alpha CD.

Example 1 of Wagu discloses a mixture of eicosapentaenoic acid (C20:5) and beta CD in a molar ratio of 1:1.5. This mixture is not stable, because beta cyclodextrin does not allow the making of stable complexes. Even when following the argument of the Examiner presented in the final office action that eicosapentaenoic acid teaches a man skilled in the art how to handle an omega-6-fatty acid, this teaching/mixture of Wagu does

not disclose the correct cyclodextrin nor does it disclose the right mixing ratio of the compounds.

In example 2, Wagu discloses a mixture of methyl eicosapentaenoate (C20:5) and gamma CD in a molar ratio 1:1.5. This complex is not stable, because gamma cyclodextrin does not allow making stable complexes. Thus, the same argument is true for this example as for example 1.

In example 3, Wagu discloses a mixture of ethyl docosahexaenoate (C22:6) and alpha CD in a molar ratio 1:2. This complex is not stable, because gamma cyclodextrin does not allow the making of stable complexes, and beta cyclodextrin does not allow making stable complexes in the mixing ratio used here. Therefore, with respect to the mixing ratio, the same argument is true for this example as for example 1. Because the wrong mixing ratio prevents the complex building here, this example does not give any hint that alpha CD might be better to make complexes than beta or gamma CD.

In example 4, Wagu discloses a mixture of beta CD and a mixture of eicosapentaenoic acid (C20:5) and docosahexaenoic acid (022:6) (from natural sardine oil). The mixture of eicosapentaenoic acid and beta CD has a molar ratio of 1:11 and the mixture of docosahexaenoic acid and beta CD has a molar ratio of 1:18. This complex is not stable, because gamma cyclodextrin does not allow making stable complexes, and beta cyclodextrin does not allow making stable complexes in the mixing ratio used here. Thus, the same argument is true for this example as for example 1.

In example 5, Wagu discloses a mixture of beta CD and a mixture of sodium eicosapentaenoate (C20:5) and methyl docosahexaenoate (C22:6) (from methyl esters of sardine oil). The mixture of sodium eicosapentaenoate and beta CD has a molar ratio of 1:11 and the mixture of methyl docosahexaenoate and beta CD has a molar ratio of 1:23. This mixture is not stable, because beta cyclodextrin does not allow making stable complexes. Thus, the same argument is true for this example as for example 1.

In example 6, Wagu discloses a mixture of methyl eicosapentaenoate (C20:5) and beta CD in a molar ratio of 1:6.5. This mixture is not stable, because beta cyclodextrin does not allow making stable complexes. So the same argument is true for this example as for example 1.

A comparison of the teaching of Wagu and the teaching according to the present claims looks as follows:

Application	Fatty acid FA	Cyclodextrin (CD)	Ratio FA:CD
Wagu	Omega-3 Fatty Acids (C20:5 or C20:6)	$\alpha$ -CD, $\beta$ -CD or $\gamma$ -CD (none preferred)	1:1.5; 1:2, 1:11, 1:18, 1:23, 1:6
Wagu + Koulbanis	Omega-6 Fatty Acid (C18:2)	$\alpha$ -CD, $\beta$ -CD or $\gamma$ -CD (none preferred)	1:1.5, 1:2, 1:11, 1:18, 1:23, 1:6
present application	Omega-6 Fatty Acid (C18:2)	$\alpha$ -CD	1:3 or 1:4

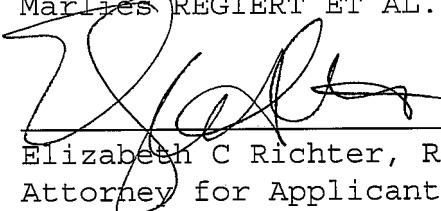
When comparing all these features, it is obvious that the teaching of Wagu does not disclose the very clear and limited features present claim 1. Even if one combines the teachings of Wagu and the linoleic acid of Koulbanis, this will not result in or make obvious the present invention. This can be seen by comparing line 2 and 3 of the above chart. The special ratio of

3:1 and 4:1 is not disclosed or obvious at all. Only when using this ratio and an alpha CD, a stable complex results, and this is just what the present claims cover.

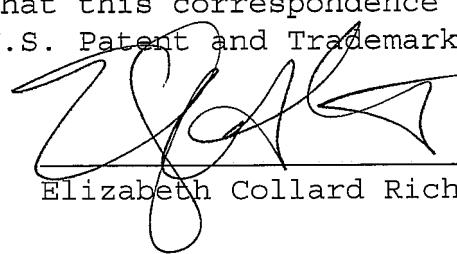
Accordingly, Applicants submit that the claims are patentable over the cited references, taken either singly or in combination. Early allowance of the amended claims is respectfully requested.

Respectfully submitted,  
Marlies REGIERT ET AL.

COLLARD & ROE, P.C.  
1077 Northern Boulevard  
Roslyn, New York 11576  
(516) 365-9802

  
Elizabeth C Richter, Reg. No. 35,103  
Attorney for Applicants

I hereby certify that this correspondence is being filed electronically in the U.S. Patent and Trademark Office on May 13, 2009.

  
Elizabeth Collard Richter